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|--|-------------|------------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/038,487   | 01/04/2002  | Nannette M. VanAntwerp | PD-0268 DIV 2       | 6491             |
| 23608  | 7590        | 12/28/2006             | EXAMINER            |                  |
| MEDTRONIC MINIMED INC.<br>18000 DEVONSHIRE STREET<br>NORTHRIDGE, CA 91325-1219 |             |                        | GILBERT, ANDREW M   |                  |
|  |             |                        | ART UNIT            | PAPER NUMBER     |
|  |             |                        | 3767                |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE   |             | MAIL DATE              | DELIVERY MODE       |                  |
| 3 MONTHS   |             | 12/28/2006             | PAPER               |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/038,487             | VANANTWERP ET AL.   |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Andrew M. Gilbert      | 3767                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 November 2006.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 36-59 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 36-59 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 04 January 2002 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/13/2006 has been entered.

### **Acknowledgements**

2. This office action is in response to the reply filed on 11/13/2006.  
3. In the reply, the applicant amended claims 36, 43, 48, 55, and 58. Thus, claims 36-59 are pending.

### ***Claim Objections***

4. Claim 53 recites the limitation "the at least one lumen of the cannula" in lns 1-2. There is insufficient antecedent basis for this limitation in the claim.  
5. Claim 59 recites the limitation "the at least one lumen of the cannula" in lns 1-2. There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 36-39, 41-44, 46-51, 53-56, 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony (5522803).

8. Teissen-Simony discloses an insertion set (Fig 1) having a mounting base (1); an infusion tubing (4), wherein the infusion tubing includes a connector (3) fixedly attached to one end of the infusion tubing; wherein the infusion tubing is adapted for delivering fluid through the connector to the insertion set (Figs 1-16; Summary); a cannula (2) coupled to the mounting base (Fig 2, 5), wherein the cannula has a distal end protruding from the mounting base (2, Fig 2, 5); the cannula is in fluid communication with the infusion tubing (Figs 1-16; Summary); an insertion needle (51) having a distal end protruding from the mounting base (Fig 15, 16), wherein the insertion needle surrounds the inside of the cannula (51, 2, Fig 15, 16), and the insertion needle is withdrawable from the mounting base after the cannula is placed at the selected insertion site (Fig 15, 16; col 6, Ins 31-62); and an adhesive patch (col 2, Ins 29-31) attached to an underside surface of the mounting base; and wherein the at least one lumen of the cannula is also adapted for withdrawing fluid from the patient (5, Summary; wherein the Examiner notes that the device is fully capable capable of being attached to a syringe or pump that is fully capable of creating a suction within infusion tubing and thus the cannula resulting in a withdrawal of fluid).

9. Furthermore, Teissen-Simony discloses the connector having a pair of resilient latch arms; and the mounting base includes a pair of recesses (Fig 8, 27, 28) adapted for snap-fit and releasable engagement with the pair of resilient latch arms on the connector (Fig 13, 31, 33, 32, 34).

10. However, Teissen-Simony does not expressly disclose the connector having a pair of recesses adapted for coupling the infusion tubing to the insertion set; and the mounting base includes a pair of resilient latch arms rearwardly projecting from the mounting base and adapted for snap-fit, releasable engagement with the pair of recesses on the connector. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the resilient latch arms provided on the connector and the recesses provided on the mounting base as taught by Teissen-Simony with the visa versa wherein the resilient latch arms are provided on the mounting base and the recesses are provided on the connector since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

11. Claims 40, 45, 52, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Teissen-Simony in view of Lord et al (5390671). Teissen-Simony discloses the invention substantially as claimed except for wherein the cannula further includes at least one lumen for receiving at least a portion of a flexible sensor, the sensor having a distal segment protruding from the mounting base with at least one sensor electrode. Lord et al teaches that it is known to have wherein the cannula further includes at least one lumen for receiving at least a portion of a flexible sensor therein, the sensor having a distal segment protruding from the mounting base (Figs 1-3) with at least one sensor electrode for the purpose of easily placing a sensor on a patient with the sensor electrodes in direct contact with patient blood so that appropriate

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blood chemistry readings can be taken. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sensor as taught by Teissen-Simony with the sensor as taught by Lord et al for the purpose of easily placing a sensor on a patient with the sensor electrodes in direct contact with patient blood so that appropriate blood chemistry readings can be taken.

***Response to Arguments***

12. Applicant's arguments with respect to claims 36-59 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Douglas et al (6749589); Fischell (5545143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

